

# EXHIBIT 3

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<p>1 Q. Fair enough.      2 Doctor, I noticed, going      3 back to your supplemental list of      4 materials, Exhibit No. 4 --      5 A. Okay.      6 Q. -- that you were provided      7 with reports of three of the plaintiffs      8 other experts, Dr. Leffler, Tackett, and      9 Lebwohl.      10 A. Yes.      11 Q. You were not provided,      12 however, with a copy of Dr. Hutfless'      13 report, were you, sir?      14 A. Hutfless?      15 Q. Hutfless, H-U-T-F-L-E-S-S?      16 A. No.      17 Q. Does that name even sound      18 familiar?      19 A. It does not.      20 Q. I'll represent to you, sir,      21 that she is an epidemiologist retained by      22 the plaintiffs to offer opinions in this      23 case.      24 A. Okay.</p>	<p>1 patients had abdominal pain, but      2 nothing serious.      3 So we were kind of looking      4 to see is there a broader -- part      5 of what we were looking for was,      6 is there a broader range of injury      7 either caused by olmesartan or by      8 other ARBs, and I would agree that      9 we did not have a striking      10 difference amongst any of the      11 groups.      12 BY MR. PARKER:      13 Q. Those patients, the 20, came      14 in with complaints of abdominal pain.      15 A. Right.      16 Q. With a history of taking      17 olmesartan.      18 A. Uh-hum.      19 Q. What made them not      20 sprue-like enteropathy patients?      21 A. Well, several reasons: One      22 is that none of the patients was      23 dechallenged, ever, so all we would -- I      24 think that there is a distinction to be</p>
<p>1 Q. I'll represent to you      2 further, Doctor, that in discussing your      3 paper, the one we talked about in 2015      4 where you looked at 20 and 20, 20, 20,      5 that she wrote that that paper does not      6 contribute to evidence of causality or      7 causation.      8 Assuming I've made the      9 representation accurately -- I believe I      10 have -- do you agree or disagree with      11 that conclusion of hers?      12 MR. SLATER: Objection.      13 THE WITNESS: I think that I      14 would agree that that paper does      15 not make a very significant impact      16 to the story of causation; and,      17 really, I would also point out      18 that, you know, those were not      19 olmesartan enteropathy patients      20 that we were looking at. We were      21 specifically trying to just      22 approximate your typical GI clinic      23 patient who maybe has something --      24 they have a complaint, these</p>	<p>1 drawn here between the spectrum of the      2 variability that can be seen in      3 olmesartan enteropathy and the more      4 common presentations.      5 A very nonspecific, mild      6 complaint like abdominal pain in a      7 patient who happens to take olmesartan,      8 is never taken off olmesartan, and never      9 has any response or lack of response      10 documented, that is not an olmesartan      11 enteropathy patient.      12 If those patients had -- if      13 the gastroenterologists in those cases      14 had decided to take them off olmesartan      15 and it had had some impact on them, then      16 we could talk about them potentially      17 being olmesartan enteropathy patients.      18 Q. So let me make sure I      19 understand. These 20 patients were seen      20 at Columbia; correct?      21 A. Uh-hum.      22 Q. They came in with abdominal      23 pain to such a degree that they end up      24 having an invasive procedure, an</p>

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<p>1 endoscopy; correct?</p> <p>2 A. A common indication for a 3 common procedure.</p> <p>4 Q. Where snips of their tissue 5 were taken out and studied.</p> <p>6 A. Uh-hum.</p> <p>7 Q. With knowledge that they 8 were taking olmesartan; correct?</p> <p>9 A. Uh-hum.</p> <p>10 Q. And the GIs at Columbia 11 said, go on home, and they didn't tell 12 them to stop taking olmesartan?</p> <p>13 A. To the best of my knowledge, 14 they did not.</p> <p>15 Q. And how long was -- did this 16 -- how long ago were these series of 20 17 patients seen with abdominal pains, 18 endoscopy results, and told -- knowing 19 they had olmesartan -- just go on home 20 and continue with your olmesartan?</p> <p>21 MR. SLATER: Objection; lack 22 of foundation.</p> <p>23 THE WITNESS: Sorry. What 24 was the question again?</p>	<p>1 ladies, we should go back and call these 2 20 people and tell them maybe they should 3 stop taking their olmesartan?</p> <p>4 MR. SLATER: With that same 5 tone of voice, that -- that 6 condescending we're a bunch of 7 idiots voice that you're throwing 8 out there, Bruce?</p> <p>9 MR. PARKER: I wouldn't say 10 it was condescending. I would say 11 I would be incredulous if I were 12 at Columbia and realized they 13 hadn't been told and given your 14 views on this. Incredulous is the 15 tone I was trying to convey.</p> <p>16 MR. SLATER: It's 17 argumentative. We're almost 18 there. Let's just take it easy.</p> <p>19 BY MR. PARKER:</p> <p>20 Q. Did you ever propose to your 21 colleagues after you did this study that 22 someone should make an effort and go back 23 and talk to these people?</p> <p>24 MR. SLATER: Objection.</p>
<p>1 BY MR. PARKER:</p> <p>2 Q. Was this relatively -- I 3 mean, your paper is 2015.</p> <p>4 A. Uh-hum.</p> <p>5 Q. When were these series of 20 6 people seen at Columbia?</p> <p>7 A. Oh, from what years did we 8 get the patients, do you mean?</p> <p>9 Q. Yes, sir.</p> <p>10 A. I'll have to check.</p> <p>11 Q. That's Exhibit 12 if that's 12 helpful. Well, you can probably find it 13 faster in your book.</p> <p>14 (Pause.)</p> <p>15 THE WITNESS: I don't think 16 that we reported the years from 17 which the biopsies were taken. I 18 think, to the best of my 19 recollection, it was maybe five or 20 six years prior to the publication 21 of this article, so --</p> <p>22 BY MR. PARKER:</p> <p>23 Q. And when you did your work, 24 did you say to your colleagues, guys,</p>	<p>1 You can answer.</p> <p>2 THE WITNESS: Okay. We 3 talked about whether we thought -- 4 whether we thought there was a 5 reason to or not, and we decided 6 that there wasn't and the reasons 7 being, one, although there was a 8 trend, it's a negative study. The 9 P value is less than -- is more 10 than .05, so we didn't have a 11 definitive -- we couldn't assess 12 causality or infer causality from 13 something with only a trend and 14 not a statistically significant 15 difference --</p> <p>16 BY MR. PARKER:</p> <p>17 Q. But your views throughout 18 today had been, if you had called back 19 those 20 people still taking olmesartan, 20 perhaps still having abdominal pain after 21 all those years and you said stop taking 22 olmesartan and they stopped taking it and 23 the pain went away, that would prove 24 causation. Right?</p>

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<p>1       A. If a patient, whether 2 they're one of these 20 or not, had a 3 symptom and the only change that was made 4 was discontinuation of a medication and 5 that resulted in the resolution of their 6 symptom, then, yes, I would think that 7 that is some evidence that it was 8 causative.</p> <p>9       Q. Let's turn to a different 10 area.</p> <p>11      A. Okay. I'm just going to 12 grab some water. I'll be right back.</p> <p>13      Q. Sure, sure. Take your time. 14           Doctor, I want to explore 15 another area and if this is getting into 16 the clinical realm and you don't feel 17 comfortable, tell me and I'll go on.</p> <p>18           Is it your view, Doctor, 19 that a patient has to take olmesartan for 20 some period of time before any GI 21 symptoms that develop can be said to be 22 olmesartan enteropathy if they go away 23 when you stop taking the drug?</p> <p>24      A. I would say that the</p>	<p>1 an increase in the symptoms? 2       A. Quickly. 3       Q. What does that mean? Hours 4 or days? 5       A. Hours to days. 6       Q. So in your understanding, a 7 -- well, strike that. Let me make a 8 foundation. 9           Is celiac also a 10 delayed-type hypersensitivity reaction? 11          MR. SLATER: Objection. 12          You can answer. 13          THE WITNESS: No. 14          BY MR. PARKER: 15           Q. What is your understanding 16 of the time course that the body needs to 17 mount an attack to something through a 18 delayed-type hypersensitivity reaction? 19 Is it hours or is it days? 20       A. I don't know. 21       Q. Now let's go back to my 22 question, Dr. Lagana. I want to go back 23 to what I started to ask you to make sure 24 I better understand your views on the</p>
<p>1 literature supports that there's a pretty 2 long lag time, on the order of months to 3 years, before olmesartan enteropathy 4 develops.</p> <p>5       So I would say that maybe 6 not in all cases, but most of the cases 7 do involve a fairly long exposure before 8 the syndrome develops.</p> <p>9       And I'll say that's also in 10 the primary context. The rechallenge 11 data is pretty notable in that once the 12 -- once the pump is primed for this 13 reaction, it does appear that people get 14 their relapses very quickly upon 15 reintroduction of olmesartan.</p> <p>16      Q. Before I go on to my next 17 question, you just said something that 18 makes me think about this: When someone 19 is diagnosed with celiac disease and they 20 go on a gluten-free diet and have 21 improvement of their GI symptoms and then 22 resume gluten in their diet, what has 23 been your experience of the time course 24 in which they resume having symptoms or</p>	<p>1 time course that's needed to be on drug 2 before, if GI symptoms were to develop, 3 you might call them sprue-like 4 enteropathy. Okay? Let me try to flesh 5 that out for you. 6       A. Okay. 7       Q. If someone starts taking -- 8 well, let me ask a foundational question: 9 Is it your understanding that ARB drugs, 10 ACE drugs, other hypertension drugs, are 11 commonly associated with diarrhea? 12       A. Define "commonly." 13       Q. Well, do physicians who 14 prescribe that drug recognize and see in 15 their clinical practice that patients at 16 times within days of starting that drug 17 -- those drugs -- excuse me -- develop 18 diarrhea? 19       A. I would think so. I don't 20 see patients in an office, so I don't 21 have firsthand knowledge of that, but I 22 believe so. 23       Q. If someone starts taking 24 olmesartan and with two or three days</p>

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<p>1 into taking the drug develop diarrhea,      2 and then after two days of diarrhea, they      3 stop the olmesartan and the diarrhea      4 stops, is that a case of sprue-like      5 enteropathy?</p> <p>6 A. I wouldn't classify it that      7 way. I would classify it as an adverse      8 drug reaction, diarrhea, but I would not      9 think that fits criteria for sprue-like      10 enteropathy associated with olmesartan.</p> <p>11 Q. Now let me go the other      12 extreme and let's say, after two years on      13 the drug, someone develops diarrhea and,      14 after two days, they just stop the drug      15 and the symptoms go away. Are those two      16 days of diarrhea sprue-like enteropathy?</p> <p>17 A. They had two days of      18 diarrhea?</p> <p>19 Q. Yeah, and then they stopped,      20 the diarrhea goes away. So both cases,      21 diarrhea for two days. One, it starts      22 two years after you start the drug, the      23 other one two days after you start the      24 drug.</p>	<p>1 hypothetical situation and those      2 are the only facts that exist in      3 this vacuum, I would say that that      4 question is not entirely -- it's      5 not entirely knowable.</p> <p>6 BY MR. PARKER:</p> <p>7 Q. And what is it about the      8 person who has been taking for two years,      9 develops diarrhea, stops the drug after      10 two days of diarrhea, and the diarrhea      11 goes away, what is unknowable about that      12 case the way you look at causation to      13 determine whether that's sprue-like      14 enteropathy?</p> <p>15 MR. SLATER: Objection.      16 You can answer.</p> <p>17 BY MR. PARKER:</p> <p>18 Q. What else would you have to      19 know?</p> <p>20 A. Okay. Let me think for a      21 moment before I answer you.</p> <p>22 Q. Sure.      23 (Pause.)</p> <p>24 THE WITNESS: So in your</p>
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<p>1 A. Could you repeat the      2 question, please? I'm not sure I      3 understood.</p> <p>4 Q. Sure. I'm trying get an      5 understanding. You said to me -- but if      6 I was wrong, correct me -- if someone      7 starts taking olmesartan and two or three      8 days into taking the drug, they develop      9 diarrhea and after two days they stop the      10 olmesartan and it goes away, you said, I      11 wouldn't characterize that as sprue-like      12 enteropathy.</p> <p>13 A. Yes.</p> <p>14 Q. Okay.</p> <p>15 Now, if someone has been on      16 the drug for two years and then develops      17 diarrhea one day and, after two days of      18 diarrhea, stops taking olmesartan and the      19 diarrhea stops, does that now become a      20 case of sprue-like enteropathy?</p> <p>21 MR. SLATER: Objection to      22 the form.</p> <p>23 You can answer.</p> <p>24 THE WITNESS: Well, in that</p>	<p>1 initial premise, two days would be      2 a very short period of time to      3 cause an organic change to the GI      4 tract, which is why I was pretty      5 comfortable excluding your initial      6 patient as an olmesartan      7 enteropathy patient.</p> <p>8 In the second case, two      9 years is plenty of time for an      10 organic change to develop. The      11 most typical case of olmesartan      12 enteropathy that we've seen has      13 involved chronic diarrhea. That's      14 not all of them. That's an      15 example, but that's been defined      16 as 30 days or more of diarrhea.</p> <p>17 Two days of diarrhea is an      18 extremely common scenario. The      19 person might have eaten something      20 bad. But if you showed me a      21 biopsy done while they were having      22 diarrhea, if it had histologic      23 features that were suggestive of      24 olmesartan enteropathy, and the</p>

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<p>1 patient truly stopped having those      2 features -- those symptoms after      3 stopping the olmesartan, I would      4 certainly consider the possibility      5 that they might have had early      6 olmesartan enteropathy.</p> <p>7 BY MR. PARKER:</p> <p>8 Q. It is your view, is it not,      9 sir, that the only medical intervention      10 that's needed in someone who you will say      11 has sprue-like enteropathy is just stop      12 taking olmesartan and you'll have      13 complete recovery?</p> <p>14 MR. SLATER: Objection.      15 You can answer.</p> <p>16 THE WITNESS: Okay.</p> <p>17 MR. SLATER: I'm not sure I      18 understood it.</p> <p>19 THE WITNESS: Yeah, can you      20 repeat that for me, please?</p> <p>21 MR. PARKER: Sure.</p> <p>22 THE WITNESS: Thank you.</p> <p>23 BY MR. PARKER:</p> <p>24 Q. Isn't it your view of</p>	<p>1 related to treatment or to      2 diagnosis or both?</p> <p>3 MR. PARKER: Treatment. I      4 said all you need to do is to tell      5 them to stop taking olmesartan.</p> <p>6 THE WITNESS: Well, some of      7 these patients come in with      8 terrible dehydration and kidney      9 damage, so if you don't rehydrate      10 them, they'll die --</p> <p>11 MR. PARKER: My example was      12 two days of diarrhea.</p> <p>13 THE WITNESS: Okay.</p> <p>14 MR. SLATER: Your question      15 was different, though, the one you      16 just asked there. So with all due      17 respect to him, you actually asked      18 a broader question.</p> <p>19 THE WITNESS: So, yes, I      20 don't think that in every case      21 simply holding olmesartan is the      22 absolute only intervention that's      23 required for those patients.</p> <p>24 BY MR. PARKER:</p>
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<p>1 causation as expressed here that if      2 somebody has developed sprue-like      3 enteropathy associated with olmesartan,      4 all you need do is to tell them to stop      5 taking the olmesartan and they will have      6 complete remission?</p> <p>7 A. No, I think that that's      8 definitely mischaracterizing my      9 statements on the topic. I will clarify,      10 though.</p> <p>11 MR. SLATER: He's not asked      12 you to, actually. If he wants you      13 to, he'll ask you to.</p> <p>14 MR. PARKER: No, I wasn't      15 going to because I got time      16 problems.</p> <p>17 BY MR. PARKER:</p> <p>18 Q. Could you turn to reference      19 --</p> <p>20 A. I would like to.</p> <p>21 MR. SLATER: Okay. I'm      22 sorry.</p> <p>23 THE WITNESS: First off, I'd      24 like to know, was that question</p>	<p>1 Q. Let me ask you to pull up      2 the exhibit -- well, it's your 2016      3 paper.</p> <p>4 A. The review article?</p> <p>5 Q. Yes, systematic review.</p> <p>6 A. Okay.</p> <p>7 Q. Exhibit 10.</p> <p>8 A. Okay.</p> <p>9 (Pause.)</p> <p>10 MR. PARKER: It might be      11 easier to find it on the desk.</p> <p>12 THE WITNESS: Let's see. I      13 got it.</p> <p>14 MR. PARKER: This is yours.      15 That's not an exhibit.</p> <p>16 THE WITNESS: Okay. Thank      17 you.</p> <p>18 BY MR. PARKER:</p> <p>19 Q. You got it?</p> <p>20 A. I got it.</p> <p>21 Q. Let's go to the last page of      22 that article. Above references -- there      23 you go -- and do you not say, "Cessation      24 of olmesartan results in complete</p>

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<p>1 resolution of both clinical and      2 histologic features"?      3 A. I say that and that's true.      4 I don't believe I said that that happens      5 100 percent of the time completely.      6 Q. Well, you sure don't qualify      7 it in saying "in some patients," do you?      8 MR. SLATER: Objection;      9 argumentative. Is there a      10 question?      11 MR. PARKER: Yeah.      12 MR. SLATER: It's an      13 argumentative question.      14 MR. PARKER: You do not say      15 in this paper anywhere that only      16 some of the people who you take      17 off olmesartan will have complete      18 resolution of clinical and      19 histologic symptoms.      20 MR. SLATER: Objection;      21 foundation, argumentative.      22 THE WITNESS: In my      23 experience, the overwhelming      24 majority of patients who I have</p>	<p>1 had complete resolution of their      2 symptoms and feel great after      3 stopping olmesartan.      4 So what I said here, I stand      5 by. I think it's true. Does it      6 apply to every single patient?      7 Probably not.      8 MR. PARKER: Okay.      9 BY MR. PARKER:      10 Q. So go back to my example.      11 I'm still trying to understand what makes      12 a case of sprue-like enteropathy and what      13 doesn't.      14 If the patient has developed      15 diarrhea after starting the drug after      16 two days and has diarrhea for two days,      17 how is that case of diarrhea clinically      18 any different than the patient who's been      19 on the drug for two years, has two days      20 of diarrhea and stops the drug, and the      21 diarrhea goes away?      22 A. Well, I want to say object      23 to foundation, because two days -- two      24 days would be really not the typical</p>
<p>1 seen the biopsies for have had      2 complete resolution of their      3 histologic changes.      4 So I've seen patients who      5 had flat, small intestinal mucosa,      6 who had fibrosis, who had patterns      7 of injury that when I was in med      8 school were associated with high      9 mortality -- actually, collagenous      10 sprue was recently a pretty deadly      11 disease in a lot of patients --      12 I've seen patients with that      13 histology go from that to looking      14 totally normal by biopsy, from      15 looking as if they just walked in      16 the street -- walked in off the      17 street feeling great, and that's      18 the vast majority of cases I've      19 seen.      20 I've seen very few cases      21 that had any residual damage; and      22 through discussion with my      23 clinical colleagues, most of the      24 patients that they've seen have</p>	<p>1 presentation of an olmesartan enteropathy      2 patient, so -- most of these patients      3 that we're talking about, we're not      4 talking about two days of diarrhea.      5 So let me say that I think      6 that the hypothetical situation is flawed      7 because two days is not really a      8 sufficient amount of time for us to think      9 about what we believe to be a fairly      10 uncommon entity when things like, you      11 know, eating a bad sandwich are common      12 and cause two days of diarrhea all the      13 time.      14 So I don't like the premise      15 of the question.      16 Q. Okay. You don't like the      17 premise of the question.      18 Doctor, nobody gets chronic      19 diarrhea overnight. Right?      20 MR. SLATER: Objection.      21 You can answer.      22 THE WITNESS: Right.      23 Chronic diarrhea is defined as      24 four weeks.</p>

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<p>1 BY MR. PARKER:</p> <p>2 Q. Right. So in your view of 3 causality, if someone has been on 4 olmesartan, develops diarrhea, and for 5 any reason, their spouse, their doctor, 6 whatever, or they decide to stop taking 7 olmesartan, you would expect them to have 8 complete relief.</p> <p>9 MR. SLATER: Objection.</p> <p>10 THE WITNESS: Can you repeat 11 that? That was a little 12 confusing.</p> <p>13 BY MR. PARKER:</p> <p>14 Q. Yeah. If somebody after two 15 years of olmesartan use develops diarrhea 16 and, for whatever reason, their own sense 17 or suggestion of a doctor that may have 18 just read one of your papers, says stop 19 using olmesartan, and the diarrhea gets 20 better, that's what you would expect them 21 to do, they would get better; correct?</p> <p>22 MR. SLATER: Objection.</p> <p>23 You can answer.</p> <p>24 THE WITNESS: I would only</p>	<p>1 the sun for six hours, you ate it, most 2 likely you had food poisoning. So 3 there's a clinical judgment that goes 4 into this.</p> <p>5 Now, if I was that patient's 6 doctor and the patient had just two days 7 of diarrhea and I really -- really wanted 8 to know if that person had olmesartan 9 enteropathy or not, in that case, 10 considering that the person does not fit 11 the typical clinical description of 12 olmesartan enteropathy, which is chronic 13 diarrhea, I would suggest a rechallenge.</p> <p>14 Q. Okay. But, Doctor, the only 15 reason they don't fit the picture is 16 because there has been somebody or 17 decisions have been made to intervene and 18 stop the olmesartan; correct?</p> <p>19 MR. SLATER: Objection.</p> <p>20 You can answer. The 21 hypothetical's migrating, but you 22 can answer.</p> <p>23 THE WITNESS: There are 24 degrees of certainty for any</p>
<p>1 expect that if they had olmesartan 2 enteropathy. If they ate bad egg 3 salad, no -- I would still expect 4 them to get better, but it 5 wouldn't have anything to do with 6 the olmesartan.</p> <p>7 BY MR. PARKER:</p> <p>8 Q. And how would you then know 9 that -- if they stopped taking it, after 10 two days the diarrhea goes away, isn't 11 that dechallenge?</p> <p>12 A. That is dechallenge. But 13 then there could be rechallenge. If the 14 person said I was at a party and there 15 was some egg salad sitting around for six 16 hours and I ate that, and if I was that 17 person's doctor -- and, of course, this 18 is a clinical judgment made by the 19 doctor, not a decision -- not a 20 hypothetical situation made in the vacuum 21 of a boardroom. This is a -- if we're 22 talking about a real-world scenario, that 23 doctor would probably say, you were at a 24 party in Florida, the egg salad was in</p>	<p>1 diagnosis that one makes or 2 doesn't make. Even when you 3 exclude something and you say it's 4 not this, that doesn't usually 5 mean that you're 100 percent. It 6 means you think it's unlikely.</p> <p>7 So if a patient had just two 8 days of diarrhea and then 9 discontinued olmesartan and felt 10 better, I would not feel like the 11 patient definitely had olmesartan 12 enteropathy and I would not feel 13 that the patient definitely did 14 not.</p> <p>15 I would consider the 16 patient's clinical state and the 17 rest of the patient's scenario and 18 if it were important for the 19 patient to be able to take 20 olmesartan, I would rechallenge 21 that patient and test it.</p> <p>22 MR. PARKER: I got a few 23 minutes before I want to stop and 24 give myself some time after Mr.</p>

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<p>1 Slater does his questioning.</p> <p>2 BY MR. PARKER:</p> <p>3 Q. Doctor, we were told by</p> <p>4 letter -- I don't see it in your</p> <p>5 references -- that you were provided with</p> <p>6 some of the reports of some of the</p> <p>7 defense experts?</p> <p>8 A. Yes, I was.</p> <p>9 Q. And by memory, I recall</p> <p>10 Turner and Wilson being the two. Were</p> <p>11 there any others?</p> <p>12 A. There was one other that I</p> <p>13 glanced at. Can you mention some of</p> <p>14 them?</p> <p>15 Q. Well, there would be a</p> <p>16 Risch, a Hanson, a Popp, and a Mann.</p> <p>17 Those are the other four plus Turner and</p> <p>18 Wilson.</p> <p>19 A. Those other names don't</p> <p>20 sound familiar. Turner and Wilson, I</p> <p>21 definitely have read.</p> <p>22 Q. Do you know Dr. Turner?</p> <p>23 A. We've never met. I've heard</p> <p>24 of him.</p>	<p>1 THE WITNESS: Well, at the</p> <p>2 bottom of page 3, this report</p> <p>3 draws on the cases described in</p> <p>4 the Cartee paper and does directly</p> <p>5 infer that they're the same cases</p> <p>6 in Rubio-Tapia 2012, and I think</p> <p>7 that that's a baseless connection.</p> <p>8 (Pause.)</p> <p>9 THE WITNESS: He says all --</p> <p>10 on page 5, the first paragraph</p> <p>11 towards the end, he says all</p> <p>12 available data suggests that</p> <p>13 seronegative celiac disease</p> <p>14 remains a far more common</p> <p>15 diagnosis than ditto even in a --</p> <p>16 which is his phraseology for</p> <p>17 olmesartan enteropathy -- even in</p> <p>18 a tertiary referral center and so</p> <p>19 that he references DeGaetani. I</p> <p>20 would say "far more" is an</p> <p>21 overstatement of the data.</p> <p>22 (Pause.)</p> <p>23 THE WITNESS: Many of his</p> <p>24 opinions seem to be -- seem to</p>
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<p>1 Q. Are you familiar with the</p> <p>2 work that he has done in the field of</p> <p>3 pathology?</p> <p>4 A. I don't have much -- I have</p> <p>5 heard his name. I know he's a respected</p> <p>6 guy. I don't know him or the specifics</p> <p>7 of his work in any great depth.</p> <p>8 Q. Early on in response to one</p> <p>9 of my questions, you said, well, I had</p> <p>10 read these reports and I think it was in</p> <p>11 the context of you telling me you weren't</p> <p>12 sure that there was anybody -- or you</p> <p>13 weren't aware that anybody disagreed with</p> <p>14 causation until you started reading some</p> <p>15 of these reports. And they didn't, of</p> <p>16 course, change your mind.</p> <p>17 When you read Dr. Turner's</p> <p>18 report, was there anything factual -- I'm</p> <p>19 not asking about his opinions, but</p> <p>20 factual -- that you can tell me he's just</p> <p>21 wrong about?</p> <p>22 A. Let me take a look.</p> <p>23 Q. Please.</p> <p>24 (Pause.)</p>	<p>1 boil down to, there are variations</p> <p>2 in presentation, therefore, this</p> <p>3 doesn't exist. It's either three</p> <p>4 things or it's nothing, and I find</p> <p>5 that to be a recurring theme in</p> <p>6 this report and I also find it to</p> <p>7 be a terribly unconvincing theme.</p> <p>8 I think that if you look at</p> <p>9 any GI inflammatory disease,</p> <p>10 celiac disease, for instance, the</p> <p>11 classical Marsh grading allows for</p> <p>12 six different manifestations of</p> <p>13 the disease and that's not even</p> <p>14 counting complications.</p> <p>15 So I think a frequent theme</p> <p>16 here is variability equals</p> <p>17 nonexistence and I find that to be</p> <p>18 a specious argument --</p> <p>19 BY MR. PARKER:</p> <p>20 Q. Okay. But I was asking</p> <p>21 about facts.</p> <p>22 A. Okay.</p> <p>23 (Pause.)</p> <p>24 THE WITNESS: So I notice</p>

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<p>1 that I have left two sticky -- I      2 have two sticky notes on here. I      3 think -- do those need to be --      4       MR. PARKER: I'm not asking      5 you to give it to me. I'm just --      6       THE WITNESS: All right. I      7 just want to -- you know, I don't      8 want to be holding anything back      9 that's not supposed to be --      10      MR. PARKER: I appreciate      11 your candor, but, no, I got only      12 ten minutes left, Doctor, so I      13 want to save myself five, if you      14 could wrap it up in five minutes.      15      THE WITNESS: I will do my      16 best.      17       (Pause.)      18      THE WITNESS: Well, clearly,      19 I think he mischaracterizes my      20 2015 study quite -- quite badly.      21 Talking about the P value we      22 published of 0.34, that's a very      23 unfair characterization, because      24 we published that there was a</p>	<p>1 have taken place in the      2 literature, not only in      3 Rubio-Tapia, but also in      4 subsequent reports.      5 BY MR. PARKER:      6       Q. Rubio-Tapia didn't have any      7 rechallenge.      8       A. It didn't have controlled      9 rechallenge, meaning that it didn't have      10 planned rechallenge, but there were      11 rechallenges.      12       Q. The anecdotal report, you're      13 talking about the two patients.      14       MR. SLATER: Objection;      15 mischaracterization, lack of      16 foundation.      17       THE WITNESS: I'm talking      18 about the rechallenges which were      19 not controlled, which were      20 described in Rubio-Tapia.      21 BY MR. PARKER:      22       Q. Okay. 2012 paper.      23       A. 2012.      24       Q. Okay.</p>
<p>1 trend towards significance in the      2 olmesartan-exposed patients, as we      3 said, a P value of .1, and we      4 compared that to the P value of      5 other -- of other ARBs or compared      6 to matched controls for them of --      7 and that was .34.      8       So we were saying that      9 there's a trend towards difference      10 in the olmesartan users and no      11 trend towards difference in the      12 other ARB users.      13       So the way that Dr. Turner      14 has picked this out and      15 highlighted this in his report,      16 though factually -- the facts are      17 true, we did report that one group      18 had P equals .34, it's a very      19 unfair characterization of what we      20 published.      21       (Pause.)      22      THE WITNESS: I think on the      23 top of page 9, he also really      24 whitewashes the rechallenges that</p>	<p>1       A. And there are -- if we're      2 getting on the topic of are there other      3 rechallenges, there are rechallenges in      4 the FDA. There are rechallenges in      5 Theophile. There are rechallenges in      6 Ianiro, all of which are positive.      7       And there are more      8 rechallenges; and if we want to contest      9 this point, I would be happy to go      10 through this and point to every positive      11 rechallenge.      12       Q. I was only following up on      13 your comment about Rubio-Tapia.      14       A. Okay. I want to make the      15 point that there are quite a few positive      16 rechallenges in the literature and if you      17 want to go into that in more depth, I'm      18 willing to.      19       Q. I don't want that. I just      20 want to hear what other -- if there were      21 anything else in Turner's report that you      22 believe to be factually incorrect.      23       A. Okay. Well, I'm on the last      24 page.</p>

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<p style="text-align: right;">Page 394</p> <p>1 Q. Okay. Good news.      2 A. I think I would leave off      3 with Turner's report by saying, I      4 disagree with his conclusions. I think      5 many of them are unfair and unfounded and      6 I disagree.</p> <p>7 MR. PARKER: Okay. Thank      8 you. I'll save whatever couple      9 minutes I have until after Mr.      10 Slater's finished.</p> <p>11 MR. SLATER: On my count,      12 that's seven minutes. We're going      13 to take a break. I have to      14 organize my notes, so we'll take a      15 few.</p> <p>16 (A recess was taken from      17 6:32 p.m. to 7:05 p.m.)</p> <p>18 - - -</p> <p>19 EXAMINATION</p> <p>20 - - -</p> <p>21 BY MR. SLATER:</p> <p>22 Q. Doctor, you were asked by      23 counsel before the break about your      24 comments in terms of your -- so the</p>	<p style="text-align: right;">Page 396</p> <p>1 Q. What would need to have been      2 disclosed per the standards for      3 disclosure of a conflict for that      4 journal?</p> <p>5 A. Paid testimony.</p> <p>6 Q. Paid expert testimony?</p> <p>7 A. Yes, paid expert testimony.</p> <p>8 Q. Had you given any paid      9 expert testimony in connection with      10 olmesartan at the time this was      11 published?</p> <p>12 A. I had not.</p> <p>13 Q. Did any of the authors      14 disclose any sort of a conflict related      15 to being a consultant to any of the      16 people that may be involved with      17 olmesartan? For example, if any of them      18 were consulting for Daiichi at the time      19 it was published, did anybody disclose      20 anything like that?</p> <p>21 A. No.</p> <p>22 Q. In that article, reference 9      23 -- and we're talking about the Burbure      24 article. Right? B-U-R-B-U-R-E. Right?</p>
<p style="text-align: right;">Page 395</p> <p>1 criticisms you had of some factual      2 statements, some opinions from Dr.      3 Turner's report a few moments ago.      4 Right?</p> <p>5 A. I was asked about that,      6 yeah.</p> <p>7 Q. If you were asked the same      8 question and you were asked to go through      9 Dr. Wilson's report, could you do the      10 same thing and go through this as well in      11 detail if he asked you do that?</p> <p>12 A. Yes.</p> <p>13 Q. Now, you were asked some      14 questions about your 2016 article, your      15 systematic review and whether you      16 disclosed a, quote, unquote, conflict of      17 interest.</p> <p>18 Do you remember counsel      19 asked you about that?</p> <p>20 A. I do.</p> <p>21 Q. Did you have an opportunity      22 to look at the standards for what would      23 need to be disclosed for that journal?</p> <p>24 A. I did.</p>	<p style="text-align: right;">Page 397</p> <p>1 A. Uh-hum.</p> <p>2 Q. Okay.</p> <p>3 Reference 9 in that article      4 is what?</p> <p>5 A. Reference 9 in that article      6 is the Rubio-Tapia/Murray article on      7 collagenous sprue from 2010.</p> <p>8 Q. I might have misspoken. Let      9 me ask you a different question: What is      10 reference 24?</p> <p>11 A. Okay. Basson.</p> <p>12 Q. Were you fully aware of the      13 Basson article when you wrote this report      14 in this case?</p> <p>15 A. Yes.</p> <p>16 Q. It wasn't listed on your      17 reliance list. Was that an oversight?</p> <p>18 A. Yes.</p> <p>19 Q. Okay.</p> <p>20 Now, in this article,      21 Burbure, on page 132, there's a reference      22 under section 5 to establishing, quote,      23 the diagnosis of olmesartan-induced      24 injury. Okay?</p>

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<p>1 A. Okay.      2 Q. What does that mean,      3 olmesartan-induced injury, in that      4 article?      5 A. Well, that reflects the      6 belief that we have -- that olmesartan is      7 causing injury in this subset of      8 patients; and as I think I said      9 previously, until I read defense expert      10 reports, I had not heard any controversy      11 on that point either from my colleagues      12 or investigators at other centers.      13 We have seen it in practice.      14 We believe it. And that term is meant to      15 plainly say it.      16 Q. There was some question of      17 you, very early in the day today, and      18 there was questioning about, quote,      19 unquote, confused histopathology, about      20 being confused with that.      21 Was that meant to suggest      22 that somebody's making a mistake in terms      23 of looking at histopathology as between      24 those various entities?</p>	<p>1 that can histologically resemble      2 olmesartan enteropathy, but that would be      3 in a patient who had a bone marrow      4 transplant. So knowing the whole      5 clinical picture is vital.      6 Q. Okay.      7 I'm going to ask you now      8 about the Rubio-Tapia article from 2012      9 and I actually have the page here to save      10 time.      11 A. Okay.      12 Q. It's okay.      13 I'm looking at page 737 of      14 the article, table 3, and what is the      15 title of table 3?      16 A. "Clinical features of      17 sprue-like enteropathy associated with      18 olmesartan."      19 Q. Does it say "the" clinical      20 features of sprue-like enteropathy? Is      21 the word "the" there in that sentence?      22 A. No.      23 Q. Your reading of this table,      24 is that meant to be an exhaustive list of</p>
<p>1 A. On the differential      2 diagnosis?      3 Q. Right.      4 A. What I was trying to say is      5 that some of those entities      6 histologically can have similarities and      7 I wasn't -- I wasn't trying to say that      8 the pathologist would make a mistake by      9 calling one the other. I was saying that      10 there is histologic overlap amongst those      11 entities.      12 Q. And what's the importance of      13 clinical correlation in that context?      14 A. Well, clinical correlation      15 is vital. Certainly if one is      16 considering the diagnosis of olmesartan      17 enteropathy, knowing that the patient was      18 exposed to olmesartan would be pretty      19 important.      20 And there are other entities      21 on the differential that would need to be      22 considered that also require clinical      23 correlation. For instance, if we were      24 talking about graft versus host disease,</p>	<p>1 clinical features?      2 A. No. I think that these are      3 some features, common examples of what      4 they saw in their first 22 patients, and      5 I certainly wouldn't take this to be      6 exhaustive or exclusionary of other      7 findings.      8 Q. The last section of that      9 table says, "evidence of clinical and      10 histologic improvement after suspension      11 of olmesartan."      12 What's the significance of      13 the use of the word "improvement" there?      14 A. Well, we've discussed this a      15 few times today, whether improvement or      16 resolution is necessary.      17 I think this is      18 acknowledging that improvement is really,      19 well, in some cases, the best you can      20 hope for. Certainly you'd like to see      21 complete resolution. You've got a sick      22 patient.      23 But if you have improvement,      24 that would be strong evidence of</p>

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<p>1 causation, if that was the only thing      2 that changed.      3 Q. You were asked by counsel a      4 few minutes ago about a hypothetical      5 where he said a patient is assumed to      6 have taken olmesartan for two years and      7 then after two years develops diarrhea      8 that lasts for two days and, after those      9 two days are up, the person stops taking      10 olmesartan for whatever reason.</p> <p>11 First question on that      12 person, would the differential diagnosis      13 -- if you were looking back      14 retrospectively to try to figure out what      15 had caused the diarrhea, would the      16 differential include olmesartan      17 enteropathy? Yes or no.</p> <p>18 A. Yes.</p> <p>19 Q. If you wanted to be more      20 sure of that at the time, when the person      21 stopped taking the drug and then got      22 better, would an endoscopy provide      23 information if the person had had an      24 endoscopy at that time?</p>	<p>1 diagnosis of malabsorption) are strong      2 arguments in favor of causality."      3 Is that statement of any      4 significance to you?      5 A. Well, yeah, I think it's a      6 -- it's a strong statement. They're      7 applying the Bradford Hill criteria      8 there, or at least some of them, and I      9 think that -- well, they've said it quite      10 plainly, that their findings are strong      11 evidence in favor of causality, and I      12 agree with that.</p> <p>13 Q. You mentioned --</p> <p>14 A. And by the way, if I could      15 just mention another thing about this      16 study --</p> <p>17 Q. Sure.</p> <p>18 A. -- which I don't think that      19 we got to too specifically, when you look      20 at the strength of the association, the      21 relative risk of 5 or 10 as is seen after      22 two years of therapy on olmesartan,      23 that's a very high relative risk.</p> <p>24 Q. And why is that significant?</p>
Page 403	Page 405
<p>1 A. It certainly could, yeah.</p> <p>2 Q. Could potentially.</p> <p>3 A. Uh-hum.</p> <p>4 Q. Would a rechallenge      5 potentially provide important information      6 as well if someone wanted to be sure --      7 you know, you got better after two days.      8 Would giving the drug to the person again      9 and seeing whether it recurs, would that      10 be helpful information?</p> <p>11 A. It would.</p> <p>12 Q. And depending on the      13 findings, that would be clinical      14 information that would be factored into      15 an ultimate diagnosis?</p> <p>16 A. It would.</p> <p>17 Q. Now, looking at the Basson      18 article -- I'm just going to turn to it      19 real quick -- and looking at page 5 of      20 the article, and there's a statement here      21 on the top left, "The strength of the      22 association and the consistency with      23 reported cases (including the long lag      24 time between initiation of olmesartan and</p>	<p>1 A. Well, again, getting back to      2 the -- if we think about the Bradford      3 Hill criteria, the strength of the      4 association, the fact that there's a      5 tenfold increased risk is strong.</p> <p>6 Q. And, you know, you've      7 mentioned the Bradford Hill criteria.      8 Counsel had asked you if it was      9 specifically mentioned in your report.      10 You didn't actually name that criteria;      11 correct?</p> <p>12 A. That's true.</p> <p>13 Q. Were you fully familiar with      14 that criteria when you did your report?</p> <p>15 A. Yeah --</p> <p>16 MR. PARKER: Objection.</p> <p>17 MR. SLATER: Let me ask the      18 question again.</p> <p>19 BY MR. SLATER:</p> <p>20 Q. Were you familiar with the      21 Bradford Hill criteria when you did your      22 analysis and wrote your report in this      23 case?</p> <p>24 A. Yeah.</p>

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<p>1 Q. Okay.      2 Even though it was not      3 named, did you take into account the      4 factors in the Bradford Hill criteria in      5 doing your analysis of the available      6 information that you relied on in forming      7 your opinion?</p> <p>8 MR. PARKER: Objection.      9 MR. SLATER: You can answer.      10 THE WITNESS: Okay. I think      11 that those factors are fundamental      12 to how people in medicine think      13 about medical science, and      14 certainly I did think about them      15 and I did address them, although      16 not in the context of listing the      17 criteria point -- on a      18 point-by-point basis. But, yeah,      19 I did think about them and I did      20 try to incorporate them.</p> <p>21 MR. SLATER: And I'm just,      22 for the record, going to give you      23 a list of the Bradford Hill      24 criteria.</p>	<p>1 putting that all together, did you      2 incorporate analysis of those factors      3 that was implicit into your analysis of      4 this material?</p> <p>5 MR. PARKER: Objection.      6 THE WITNESS: Yes.</p> <p>7 BY MR. SLATER:</p> <p>8 Q. Coming back to the Basson      9 article, towards the end at the bottom of      10 page 5, there's a statement that says,      11 "Patients treated with olmesartan should      12 be informed about the risk of this      13 complication, and should be advised to      14 seek medical attention if they experience      15 gastrointestinal symptoms. This      16 information should also be widely      17 delivered to physicians of all      18 disciplines, particularly to      19 gastroenterologists who are faced to this      20 new category of patients."</p> <p>21 In the context of a question      22 of whether there's -- whether the authors      23 in this article had a viewpoint on      24 causation, is that statement I just read</p>
<p>1 BY MR. SLATER:      2 Q. Strength of association,      3 consistency, specificity, temporality,      4 biologic gradient, plausibility,      5 coherence, experimental evidence, and      6 analogy, is that one way to describe      7 those criteria?</p> <p>8 MR. PARKER: Objection.      9 THE WITNESS: Yes, I believe      10 so.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. And I'll actually -- counsel      13 objected, so I'm going to read you -- I'm      14 going to ask you a different question.</p> <p>15 With regard to the Bradford      16 Hill criteria, I'm going to list what I      17 believe to be some of those factors and      18 -- well, actually, you know what? I      19 don't need to go through it again.</p> <p>20 Are you familiar with the      21 Bradford Hill criteria factors?</p> <p>22 A. Yes.</p> <p>23 Q. In analyzing, for example,      24 the literature and your experience and</p>	<p>1 to you of any significance?      2 MR. PARKER: Objection.      3 MR. SLATER: You can answer.      4 THE WITNESS: Okay. I don't      5 think there's really any vagary to      6 that statement. I think that      7 they're expressly stating that      8 this is a new category of patient      9 that we're now aware of. I think      10 that they're saying this      11 information is important, to be      12 widely distributed. And I      13 absolutely agree.</p> <p>14 The patients that we've seen      15 at Columbia who suffered from this      16 condition have been in terrible      17 shape. Many have had      18 life-threatening illness. And      19 there's a million      20 antihypertensives on the market.      21 I -- you know, very rarely do you      22 see this degree of improvement,      23 both pathologically and      24 clinically, with a fairly simple</p>
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<p>1 intervention.      2 So I think that they were      3 clearly stating that in their      4 opinion, this is causal and a      5 powerful intervention.      6 BY MR. SLATER:      7 Q. Do doctors recommend that      8 patients be warned of a risk of taking a      9 drug if they don't think the drug causes      10 the risk?      11 MR. PARKER: Objection.      12 THE WITNESS: Could you      13 repeat --      14 MR. SLATER: Sure.      15 BY MR. SLATER:      16 Q. This statement is      17 recommending that patients be warned of      18 the risk of what they call this      19 complication.      20 A. Uh-hum.      21 Q. Would doctors make a      22 recommendation that patients be warned of      23 the risk of a complication with a drug if      24 they didn't think the drug caused the</p>	<p>1 and methods, it states in part, "For      2 inclusion into the study, the following      3 criteria had to be met," and number 3 is      4 exclusion of a medication-related      5 etiology such as olmesartan or chronic      6 nonsteroidal antiinflammatory drug      7 (NSAID) use.      8 Do you see what I just read?      9 A. I do.      10 Q. With regard to whether or      11 not the authors of this study believe      12 that olmesartan is a cause of an      13 enteropathy that we're referring to as      14 olmesartan enteropathy, those parts that      15 I just read to you, what would be the      16 significance of those sections I just      17 read with regard to that question?      18 MR. PARKER: Objection.      19 THE WITNESS: Mind if I just      20 take the (Indicating) --      21 MR. SLATER: Yeah, sure,      22 absolutely.      23 THE WITNESS: Well, they say      24 exclusion of a medication-related</p>
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<p>1 complication?      2 MR. PARKER: Objection.      3 THE WITNESS: They would      4 not.      5 MR. SLATER: Now, I just      6 have to find this one more      7 article, and I think I left it on      8 the desk, and then I'm done.      9 (Pause.)      10 BY MR. SLATER:      11 Q. I'm looking at the      12 Histopathology article that you were      13 asked about by Brown, et al?      14 A. Uh-huh.      15 Q. And in the article, I'm      16 looking at the -- page 255 and there's      17 two things that they have: They have      18 table 1 titled "Histological Mimics of      19 Celiac Disease" and, if you go down, it      20 says drugs, for example, NSAIDs,      21 olmesartan, methotrexate, mycophenolate.      22 Do you see that?      23 A. I do.      24 Q. And then under the materials</p>	<p>1 etiology such as olmesartan, so to      2 say that it's an etiology,      3 etiology is cause, so I would      4 interpret this to mean that the      5 authors of this study believe that      6 olmesartan causes enteropathy.      7 MR. SLATER: Thank you.      8 Depending on what Mr. Parker      9 does in his inestimable wisdom --      10 MR. PARKER: No, I believe      11 the rules require me to limit my      12 questions to your cross and      13 there's nothing that was said that      14 I have any other questions on.      15 You're done.      16 MR. SLATER: Thank you.      17 (Witness excused.)      18 (Deposition concluded at      19 approximately 7:23 p.m.)</p>

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<p style="text-align: right;">Page 414</p> <p>1 2           <b>CERTIFICATE</b> 3 4 5       I HEREBY CERTIFY that the 6       witness was duly sworn by me and that the 7       deposition is a true record of the 8       testimony given by the witness. 9 10      It was requested before 11     completion of the deposition that the 12     witness, STEPHEN M. LAGANA, M.D., have 13     the opportunity to read and sign the 14     deposition transcript. 15 16 17     KIMBERLY A. CAHILL, a 18     Federally Approved Registered 19     Merit Reporter and Notary Public 20     Dated: February 9, 2017 21 22     (The foregoing certification 23     of this transcript does not apply to any 24     reproduction of the same by any means, 25     unless under the direct control and/or 26     supervision of the certifying reporter.)</p>	<p style="text-align: right;">Page 416</p> <p>1 2       - - - - - 3       <b>ERRATA</b> 4 5 6       REASON: _____ 7 8       REASON: _____ 9 10      REASON: _____ 11 12      REASON: _____ 13 14      REASON: _____ 15 16      REASON: _____ 17 18      REASON: _____ 19 20      REASON: _____ 21 22      REASON: _____ 23 24      REASON: _____</p>
<p style="text-align: right;">Page 415</p> <p>1 2       <b>INSTRUCTIONS TO WITNESS</b> 3 4       Please read your deposition 5       over carefully and make any necessary 6       corrections. You should state the reason 7       in the appropriate space on the errata 8       sheet for any corrections that are made. 9 10      After doing so, please sign 11     the errata sheet and date it. 12 13      You are signing same subject 14     to the changes you have noted on the 15     errata sheet, which will be attached to 16     your deposition. 17 18      It is imperative that you 19     return the original errata sheet to the 20     deposing attorney within thirty (30) days 21     of receipt of the deposition transcript 22     by you. If you fail to do so, the 23     deposition transcript may be deemed to be 24     accurate and may be used in court.</p>	<p style="text-align: right;">Page 417</p> <p>1 2       <b>ACKNOWLEDGMENT OF DEPONENT</b> 3 4       I, _____, do 5       hereby certify that I have read the 6       foregoing pages, 1 - 418, and that the 7       same is a correct transcription of the 8       answers given by me to the questions 9       therein propounded, except for the 10      corrections or changes in form or 11      substance, if any, noted in the attached 12      Errata Sheet. 13 14 15 16      STEPHEN M. LAGANA, M.D.   DATE 17 18 19      Subscribed and sworn 20      to before me this 21      ____ day of _____, 20 _____. 22      My commission expires: _____ 23 24      Notary Public</p>

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## 1 LAWYER'S NOTES

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